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PATENT
Attorney Docket No.: DALHO1290-1
(028614-1102)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sawynok et al.

Application No.: 09/700,625

Filing Date: February 1, 2001

For: USE OF TRICYCLIC
ANTIDEPRESSANTS FOR LOCAL
ANALGESIA

Group Art Unit: 1615

Examiner: T. Ware

CERTIFICATE OF MAILING

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on the date below, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231

Stephen E. Reiter

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Signature

February 11, 2002

Date

Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

We, Jana Sawynok, Mike Esser and Allison Reid, being duly warned, hereby individually and collectively declare and say that:

1. We are the joint co-inventors of the invention disclosed and claimed in the above-referenced application.
2. We understand that October 28, 1997 is the effective prior art date of a reference cited by the Examiner, U.S. Patent No. 5,922, 341 to Smith and Place.
3. The present invention was completed prior to October 28, 1997 during experiments performed at Dalhousie University, Halifax, Nova Scotia, Canada.

4. The attached documents (Appendices A-C) are submitted as evidence of the conception and completion of the present invention prior to October 28, 1997. These documents are true and complete copies of experimental data files preserved on computer diskettes created after experiments were conducted, except all dates have been deleted therefrom. We attest that all of the redacted dates are earlier than October 28, 1997.

5. Prior to October 28, 1997, we conceived the idea of using an antidepressant in a composition to be locally administered for local analgesia. This idea was then reduced to practice in experiments recorded in Appendices A-C.

6. Specifically, prior to October 28, 1997, we conducted the experiments summarized in Appendices A-C with compositions to achieve local administration of a prototype antidepressant, amitriptyline. Furthermore, prior to October 28, 1997, we conducted experiments that demonstrate that local administration of such compositions produces local analgesia.

7. Prior to October 28, 1997, amitriptyline was used as a prototype antidepressant in a composition for local administration to rats employing the protocol described in Example 2A of the specification at pages 38-39. In this model peripheral pain test, formalin is administered into the dorsal hindpaw of the rat, and following injections, rats are observed for flinching behaviors (lifting, shaking or rippling of the haunch) and biting/licking.

8. Prior to October 28, 1997, experiments summarized in Appendix A demonstrate that the local administration of amitriptyline at 100 nmol reduces pain responses in rats simultaneously administered 0.75 % formalin. Two groups of rats (control = formalin and test = formalin + amitriptyline) were monitored for 60 minutes post-injection. Appendix A, page 1 shows the data sets of the number of flinches observed. Appendix A, page 2 shows the data sets of the time spent biting/licking. Appendix A, page 3 is a graphical representation of these data sets, demonstrating the reduction in the number of flinches in the amitriptyline test group.